

# 2011 Military Health System Conference

## New Emerging Technology Clinical Trials Participation—Policy and Processes

*The Quadruple Aim: Working Together, Achieving Success*

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24 January 2011

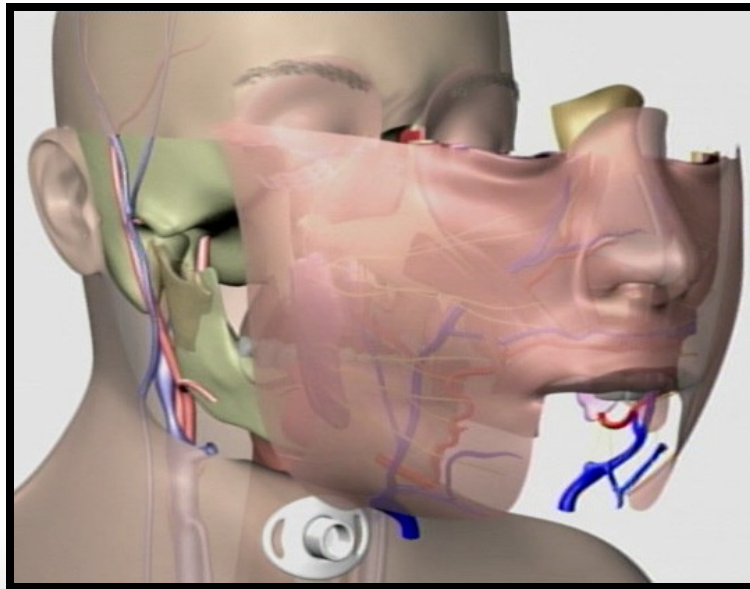


US Army Office of The Surgeon  
General

# Outline



- Background
- Policy Overview
- Advisory Board Overview
- Waiver Process
- Summary



# Amputees and Spinal Cord Injured



- 1145 OIF/OEF amputee patients (as of 1 Dec)
  - 227 with upper extremity amputations (20%)
  - 11 of the 227 are bilateral
  - 7 of 227 are shoulder disarticulations
  - 293 of 1145 are multiple

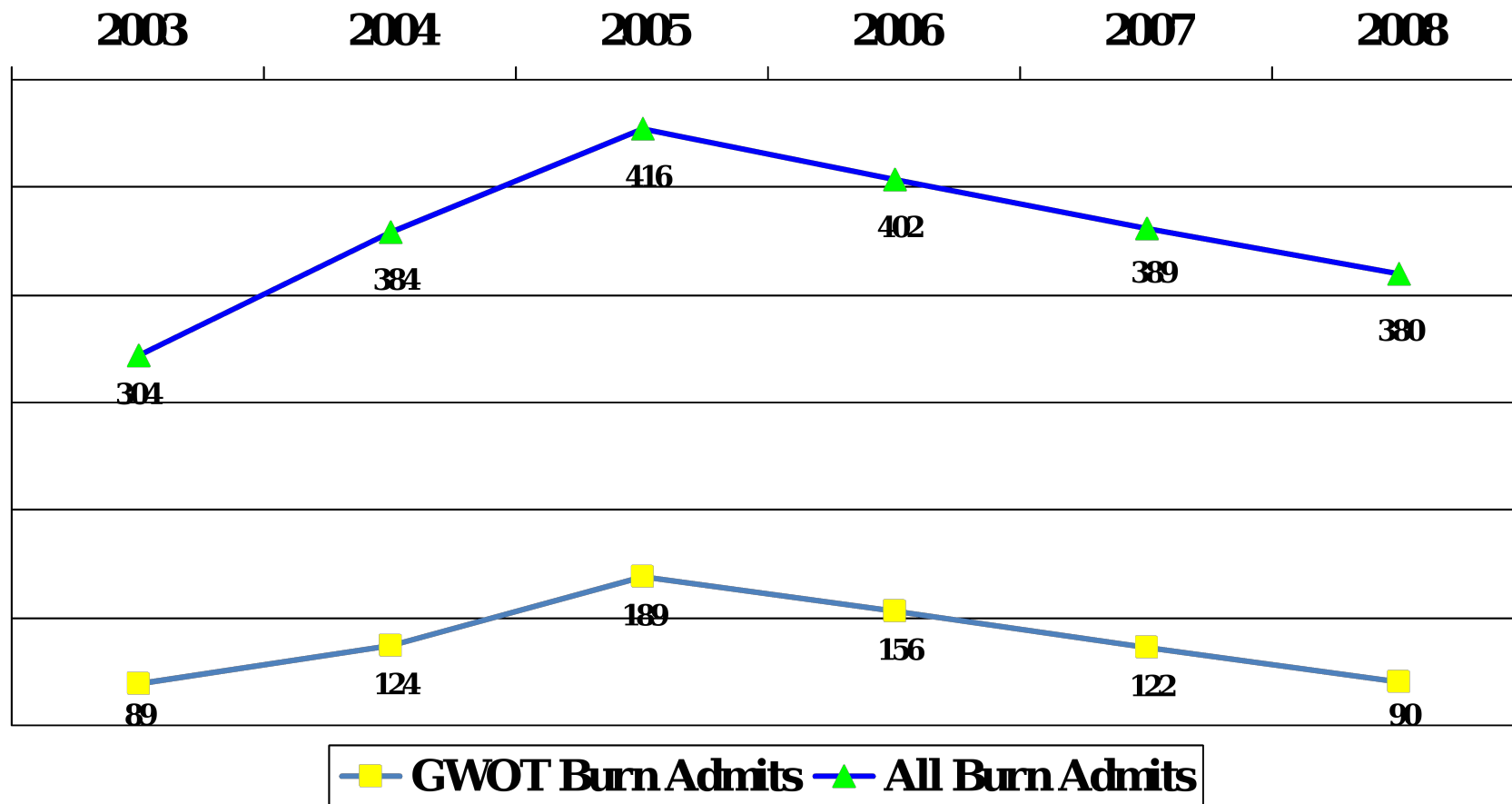


- Spinal Cord Injuries: approx 150/year in US Armed Forces (active component)

# Burns and Other Facial Trauma



Annual Burn Admissions to the US Army Institute for Surgical Research



# Background



- **Army saw a need for Advisory Boards**
  - Hungry for info: Internet, peers, leadership
  - Approx 50 people worldwide (some bilateral) received hand transplants
  - 1<sup>st</sup> successful one in 1998 (France)
  - 1<sup>st</sup> prolonged success: Louisville, KY (Drs Breidenbach and Tsu-Min Tsai) in 1999
  - 9 in US, including 3 bilateral
  - 14 centers in US with programs in various stages

# Background



## ■ **Timeline for Hand Transplant Policy**

- Feb 09: Approval to provide hand transplant trial info to amputees and burn patients
- 9 Mar 09: Army Policy Memo drafted
- 20 Mar 09: Advisory Board Charter
- 28 Mar 09: Patient Information Paper
- 4 May 09: Advisory Board members appointed
- 19 Jun 09: Policy and Charter approved

# Background



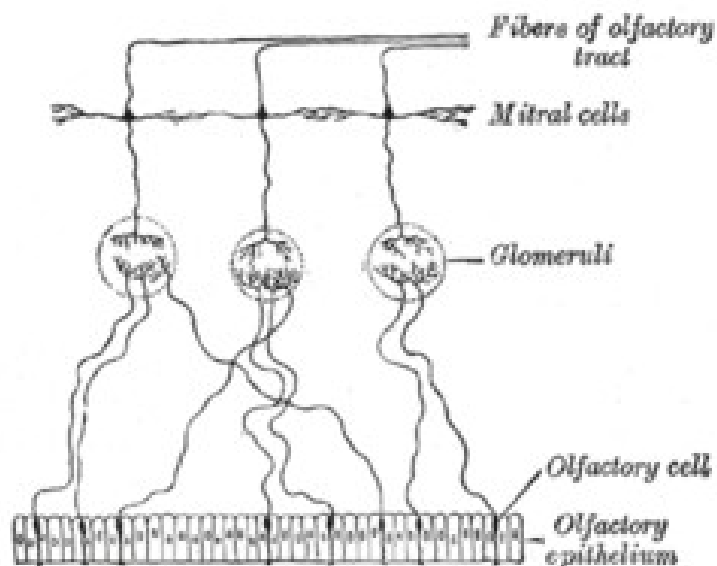
- **Timeline for Face Transplant Policy**
  - 23 Sep 09: Policy and Charter drafted
  - 19 Oct 09: Policy and Charter approved



# Background



- **Timeline for Spinal Cord Injury Policy**
  - 6 Aug 10: Policy and Charter drafted
  - 26 Aug 10: Policy and Charter approved





# Policy Overview



- **Patients**

- Unilateral or bilateral upper extremity amputees with trial of prosthesis, or burn patients
- Face trauma
- Spinal Cord Injury

- **Rehab Team/Physician** provides patient info sheet and answers questions
- **Interested patients** – meet with advisory board to ask questions on current standard and non-standard of care options

# Advisory Board Overview



- Recommend policy & procedures to TSG and oversee policy execution
- Be knowledgeable with current treatment options, to include clinical trials
- Meet with patients, Families, and providers to present facts about treatment options, answer questions, and provide assistance
- Provide TSG with proceedings and recommendations

# Advisory Board Members: Hand



- Chair + 20 members:
- Rehab (PT, OT, Physiatrist)
- Nurse Case Manager and Social Worker
- Surgeons (Ortho, Transplant, Trauma)
- VA (OTSG VA Liaison and VA reps)
- Human Protection and Research reps (MRMC)
- Amputee Program Manager and Prosthetist
- Medical Ethicist and Chaplain
- Immunologist and Pharmacist
- Psychologist
- Legal

# Waiver Process



- Advisory Board Members vote whether or not to recommend release to a non-standard of care treatment
- Chair writes Memo for TSG's approval
- With assistance from Chair, patient's provider writes waiver to staff through hospital CDR and OTSG
- Chair then sends waiver to TMA/HA
- Patients and providers notified once approved

# Summary



- 6 potential Hand Transplant recipients
  - 1 has waiver approval (quad) and on waiting list
  - 1 awaiting waiver approval and is on waiting list
  - 1 not recommended by advisory board
  - 1 chaptered out of Army
  - 1 decided to wait (Marine)
  - 1 meets with Board next month (Quad)
- 1 potential Face Transplant recipient
  - Decided to wait
- 2 Spinal Cord Injured Soldiers
  - 1 approved to go to Portugal for treatment
  - 1 awaiting waiver approval

# Thank You

